K102182

MAQUET
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MAY - 9 2011

510 (K) Summary [as required by 21 CFR 807.92(c)]

Date
May 6, 2011

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Trade name:	**Model:**	**Model number:**
FLOW-i Anesthesia System	MAQUET FLOW-i C20	6677200
	MAQUET FLOW-i C30	6677300

Device Classification

Common Name	*Classification Number*	*Class*	*Regulation Number*
Gas-Machine, Anesthesia	73 BSZ	II	21 CFR 868.5160

Predicate Device Identification

Legally marketed devices to which equivalence is being claimed	*510(k) #*
Maquet, KION Anesthesia Workstation	K024213
GE Datex-Ohmeda, Aisys Anesthesia System	K090233
Maquet, SERVO-i Ventilator System	K073179

Device Description
FLOW-i is a high-performance anesthesia system designed to meet the many ventilatory challenges within anesthesia, as well as to provide inhalation anesthesia. It is intended to serve a wide range of patients from neonatal to adult.

FLOW-i is a software-controlled circle system for inhalation anesthesia (Sevoflurane, Desflurane, Isoflurane and/or nitrous oxide).
The most important features that enhance FLOW-i performance compared with a traditional anesthesia system are:

- a ventilator whose functionality is based on ICU-ventilator technology,
- the volume reflector technology,
- the electronically controlled injector vaporizers and
- the ergonomic design.

Ventilator
The available ventilation modes in FLOW-i are manual ventilation, Volume Control, Pressure Control and Pressure Support.
The ventilator comprises electronically controlled so-called gas modules to supply the gas mixture (oxygen and air/nitrous oxide) at a dynamic flow requested for high-performance automatic ventilation, or at a constant fresh gas flow during manual ventilation. The gas modules facilitate precise control of gas flow and pressure during automatic ventilation. There are three gas modules (oxygen, air, nitrous oxide) to deliver fresh gas, and one reflector gas module (oxygen) to drive the rebreathing gas.
Pressure, flow and gas concentrations to and from the patient are monitored and displayed on a graphical user interface on a control panel. Via the graphical user interface the user can set all parameters for the ventilation modes just as in an ICU-ventilator, as well as all gas concentrations, alarm limits etc.
FLOW-i is also equipped to enable the patient to be manually ventilated with oxygen in case the system loses its electrical power (mains and battery backup).

Volume reflector
The volume reflector replaces the "bag-in-bottle" used in many traditional circle systems. It has a fixed volume of 1.2 liters and no moving parts and is open at both ends. The exhaled gas mixture from the patient is introduced at one end of the volume reflector. During automatic ventilation, the stored gas mixture in the volume reflector is returned to the patient by applying a flow of oxygen from the reflector gas module to the volume reflector's other end. Owing to the design, there is minimal mixing between the exhaled gas and the oxygen in the volume reflector. The amount of exhaled gas returning to the patient via the CO_2 absorber is determined by the ratio between the minute volume and the set fresh gas flow.
The volume reflector enables high ventilation performance. Another advantage is that the system can deliver the requested breathing gas even in case of leakage, e.g. at the tracheal tube. The volume reflector cannot be emptied like a "bag-in-bottle".

Vaporizers
The FLOW-i anesthesia delivery system uses a vaporizer with an electronically controlled injector. The gas mixture from the gas modules passes through the vaporizer chamber, where the agent is injected, before the fresh gas is delivered to the breathing circuit. The fresh gas flow varies during the inspiration phase/expiration phase in automatic ventilation. This means that the amount of added anesthetic agent also varies during the breath cycle in order to maintain the intended anesthetic agent concentration in the fresh gas.
Changes made in set agent concentrations will be instantaneous. The available setting ranges for the anesthetic agents are: Sevoflurane 0-8%, Desflurane 0-18% and Isoflurane 0-5%.

Ergonomic design
FLOW-i has many ergonomic features, e.g. it is available as a height-adjustable workstation. The control panel can be tilted or rotated and is mounted on a movable support arm, while the touch screen on the control panel enables easy access to FLOW-i functions.

Indications for Use
The indication for FLOW-i Anesthesia System is administering inhalation anesthesia while controlling the entire ventilation of patients with no ability to breathe, as well as in supporting patients with a limited ability to breathe. The system is intended for use on neonatal to adult patient populations. The system is intended for use in hospital environments, except MRI environment, by healthcare professionals trained in inhalation anesthesia administration.

Non-clinical Testing and Performance
Performance testing has resulted in data that demonstrates that FLOW-i Anaesthesia System performs within its specifications and within the acceptable limits of the applied performance standards. The following performance characteristics of FLOW-i Anaesthesia System were thoroughly tested: technical data, measurement ranges and measurement accuracy, construction, features, interfaces, handling, critical situations and interventions.

To evaluate the safety and effectiveness of the FLOW-i Anaesthesia System the following areas have been tested:

- Electrical and mechanical Safety
- Electromagnetic Compatibility
- Software Validation
- Usability
- Tightness
- Verification of Alarms
- Packaging
- Verification of Operating Data and Accuracy of Measurements
- Performance

- Biocompatibility
- Vaporizer filling system

Comparison of Technological Characteristics to Predicate Devices

Comparison of Intended Use

The intended use for the subject device and the predicate devices KION K024213 and Aisys K090233 is in all essentials the same. The devices are all intended for delivery of inhalation anesthesia for the patient ranges from neonatal to adult and shall be used by healthcare professionals trained in the administration of anesthesia in hospital environments. None of the devices is intended to be used during transport or in a MRI environment.

Comparison of Technology Used

Summary of technological characteristics of the subject device and the predicate devices: In most respects the subject device uses the same (or very similar) technology as the predicate device KION K024213, but with modern components.

The modifications are essentially as follows:

1. The mechanical vaporizers from KION K024213 are replaced with electronic vaporizers.
2. The bag-in-bottle is replaced with a volume reflector.
3. The flow transducer technology is re-used from the predicate device SERVO-i K073179.
4. The touchscreen technology is re-used from the predicate device SERVO-i K073179.

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The reasons for the modifications are:

1. The mechanical vaporizers are replaced with electronic vaporizers to facilitate a more dynamic fresh gas flow, thereby enabling better ventilation performance and faster response to changes of fresh gas settings, i.e. flow and concentrations.
2. The bag-in-bottle is replaced with a volume reflector in order to improve ventilation performance.
3. The new flow transducer is introduced to improve expiratory measurement accuracy.
4. The touchscreen is introduced to improve the usability aspects.

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Conclusion

Maquet believes that the FLOW-i is substantially equivalent to the two predicate anesthesia machines (KION K024213 and AISYS K090233) regarding intended use of the devices, the indications for use and the fundamental technology of the devices. Maquet has conducted the necessary verification and validation activities to demonstrate that the design outputs of the subject device meet the design input requirements. Maquet has concluded that FLOW-i is substantially equivalent to the two predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Document Control Room –WO66-G609
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Maquet Critical Care AB
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MAY - 9 2011

Re: K102182
Trade/Device Name: MAQUET Flow-I Anesthesia System
Regulation Number: 21 CFR 868.5160
Regulation Name: Gas Machine for Anesthesia or Analgesia
Regulatory Class: II
Product Code: BSZ
Dated: May 6, 2011
Received: May 9, 2011

Dear Ms. Törning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Anthony Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K102182

MAQUET Flow-I Anesthesia System

Indications for Use:

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Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
510(k) Number K102182